



Advancing Community Pharmacy Practice in Challenging Times



PGEU GPUE

Annual Report 2012

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Isabelle Adenot
PGEU President 2012

Foreword

Our vision of Community Pharmacy in Challenging Times

European countries face numerous challenges for public health, related to demographics, lifestyles and economics. European pharmacists share a vision for the role and the position of community pharmacists in this new world and they are ready and willing to play their part. Indeed our professional practice is rooted in the reality of modern health and society. A year in the life of PGEU is a year matching pharmacy practice and European legislation and policy with patient needs.

Patients need access to safe, high quality and genuine medicines at the right time, a need increasingly denied by the problem of medicines shortages in Europe. In 2012, PGEU called on to European and national authorities as well as other stakeholders to work together to find solutions to this appalling situation. We also signed a Memorandum of Understanding with our supply chain partners setting out the core principles of a European medicines verification system, as required by the Falsified Medicines Directive.

Patients need to be empowered and take control of their health. Pharmacists are well-positioned to support them, particularly in the field of self-medication where their information and advice are crucial. In 2012, PGEU signed a Charter of Collaboration with the Association of the European Self-Medication Industry in order to improve the use of such products.

Collaborative care is also a key area for our profession, and in 2012 we signed a joint statement with European Association of Hospital Pharmacists on future pharmacist roles, particularly in relation to medicines management, reconciliation of medicines, and medicines adherence.

Patients in Europe need pharmacists to maintain and develop our services while supporting the efficiency and quality of health systems. So in 2012 PGEU called on European governments to carefully consider cost-containment measures impacting on the sustainability of pharmacies because, ultimately, they might be counter-productive.

To respond to all these challenges, pharmacy practice itself needs to evolve. That is why, in 2012, we developed the European Community Pharmacy Blueprint. Pharmacists organisations from 32 different countries agreed on a common vision for their profession, which is in my view a very significant development.

On the legislative front too, 2012 has been very busy, with PGEU involved in a dozen pharmacy-related issues such as pharmacovigilance, medical devices, falsified medicines or cross-border healthcare. I would personally highlight the revision of the directive on the Recognition of Professional Qualifications, which has already achieved a lot for the mobility of pharmacists within Europe, without undermining patient safety.

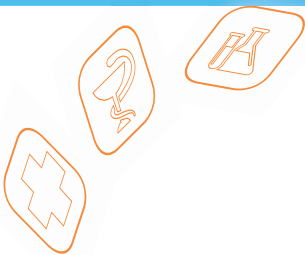
Patients need personalised advice to improve their treatment outcome. In this area, the use of health data is key, but only with high levels of protection of personal data. In 2012 PGEU supported the reinforcement of the EU legislation on Data Protection.

Minimising risks, maximising benefits was the title of our June Symposium in Paris. This is the common theme which runs through our professional life.



2012

AT A GLANCE



❖ January

- » PGEU Responded to the European Commission's (EC) Consultation on EU Prescriptions
- » EAEPC - The European Association of Euro-Pharmaceutical Companies, joined PGEU, Full line wholesalers- (GIRP) and European Federation of Pharmaceutical Industries and Associations (EFPIA) on the European Stakeholder Model (ESM) - coding and medicines authentication project
- » PGEU addressed the eTACT EDQM (Council of Europe) -medicines authentication project-workshop in Strasbourg
- » PGEU addressed Pharmacia Latina in Lisbon
- » PGEU attended the EU funded Project "Chain of Trust" Steering Group Meeting in Oslo

❖ February

- » European Commission Published new drafts proposals of Patient Information and Pharmacovigilance

- » European Commission Published new proposals and endorses a four-year action plan for Active and Healthy Ageing
- » PGEU organised the "Chain of Trust" Focus Group for pharmacists
- » PGEU attended ECJ public hearing of case C-84/11 concerning pharmacy establishment in Finland
- » PGEU attended the European UDI Ad Hoc Working Group organised by DG Sanco in the framework of the new regulation on medical devices
- » PGEU participated in the 4th EMA's Stakeholders Forum on the new Pharmacovigilance legislation
- » PGEU attended annual joint meeting of EMA's Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Group (HCP WG)

❖ March

- » European Commission proposed new Transparency Directive

- » Recognition of prescriptions: European Commission published results of the public consultation
- » PGEU published Statement "Sustainable European Community Pharmacies- Part of the Solution"
- » PGEU adopts Memorandum of Understanding on medicines authentication with EFPIA, EAEPC and GIRP
- » PGEU received the Correo Farmaceutico Award with EFPIA and GIRP in the category 'Best Initiative of the Year' in relation to the paper Ten Core Principles relating to medicines authentication
- » The Association of Private Pharmacists of Serbia (SPAS) joined PGEU
- » PGEU attended workshop related to activities of the European Innovation Partnership on Active and Healthy Ageing organised by the European Commission in London
- » PGEU spoke at Healthcare Professionals Crossing Borders (HPCB) meeting at the European Parliament

❖ April

- » PGEU attended workshop on eID for eHealth
- » PGEU participated in the workshop 'Ensuring safe and effective medicines for an ageing population' organised by EMA in London
- » PGEU, EAEPC, EFPIA, GIRP jointly responded to public consultation on the detailed rules for a unique identifier for medicinal products for human use, and its verification. In addition PGEU has submitted its individual response
- » PGEU conducted research on medicines shortages
- » PGEU attended high level conference organised by DG Health and Consumers and DG Information Society and Media on the European Innovation Partnership's Strategic Implementation Plan
- » PGEU spoke at European Pharmaceutical Students' Association Annual Congress in Istanbul (EPSA)

March
PGEU GA



May
PaSQ Joint Action Meeting in Denmark



- » PGEU attended the eHealth Governance Initiative consortium workshop on eID
- » PGEU attended the Access to Medicines Steering Group initiative on Good governance for non - prescription medicines in Copenhagen
- » PGEU spoke at the Pharmaceutical Pricing and Reimbursement (PPRI) Conference in Vienna
- » PGEU presented at conference on Information to Patients in Bratislava

March
Correo Farmaceutico Award

May
Health and Policies Pharmaceutical Forum in Cyprus



- » PGEU addressed regional GIRP meeting on Medicines Authentication in Budapest
- » PGEU addressed Pharmacy Day in Finland

✚ May

- » Pharmacovigilance: European Medicines Agency launched suspected side effect reports (ADRs) portal
- » Food Supplements: European Commission adopted list of permitted health claims
- » PGEU attended annual meeting of European Industrial Pharmacists (EIPG) in Lisbon
- » PGEU attended eHealth Week 2012 in Copenhagen
- » PGEU attended the plenary meeting of Healthcare Professionals Working Group at EMA

June
PGEU General Assembly in Paris



June
Annual Symposium in Paris



- » PGEU attended EU Health Policy Forum
- » PGEU attended Working Group on European Workforce for Health
- » PGEU attended European Conference on Chronic Diseases
- » PGEU attended the 6th European Patients' Rights Day meeting
- » PGEU attended ESIP (European Social Insurance Platform) Conference on 'Active, healthy ageing and solidarity between generations'
- » PGEU attended the Patient Safety and Quality of Care (PaSQ) Joint Action Kick-off meeting in Denmark
- » PGEU attended the steering group meeting of the EU funded project on Cross Border Health Care – ECAB- meeting in Berlin
- » PGEU addressed Annual Congress of the Croatian Pharmaceutical Society
- » PGEU presented to the Health and Policies Pharmaceutical Forum in Cyprus

✚ June

- » PGEU organized its Annual Symposium in Paris dedicated to the topic "Minimising Risks and Maximising Benefits to Patients"
- » Pharmacovigilance: Adoption and Publication of Commission Implementing Regulation on pharmacovigilance activities in the Official Journal of the European Union.
- » Antimicrobial resistance: Council adopted conclusions
- » PGEU issued a Press Release on World Anti Counterfeiting Day
- » PGEU addressed European Patients Forum (EPF) Advisory Board
- » PGEU addressed annual meeting of AESGP, the European Self Medication Association in Nice
- » PGEU attended European Public Health Alliance (EPHA) annual conference
- » PGEU attended joint SecurPharm (German authentication pilot)/ European Medicines

Verification System info session

- » PGEU addressed GIRP annual conference in Lisbon
- » PGEU addressed the European Generics Association (EGA) annual meeting in Malta
- » PGEU attended the Open Forum of European Partnership Action Against Cancer (EPAAC) in Rome
- » PGEU participated in the Patient Safety in Primary Care Expert Panel in Nottingham, UK
- » PGEU addressed the Bulgarian Pharmaceutical Days in Sofia
- » PGEU addressed the Healthy Mouth Conference at the European Parliament
- » PGEU addressed joint info session on Coding & Serialization within the EFPIA annual meeting in Brussels

✦ July/August

- » PGEU attended the European Medical Devices UDI Ad Hoc WG
- » PGEU addresses Board of Swedish Pharmacy Association

✦ September

- » Standardisation: EP adopted legislative resolution and a position on first reading
- » Professional Qualification Directive: MEP Vergnaud presented the draft report

- » Medical Devices: European Commission presented a proposal for a Regulation on medical devices
- » PGEU Responded to draft recommendation on a common framework for a unique device identification in the EU
- » PGEU attended EMA's Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Group (HCPWG) joint meeting
- » PGEU attended EFPIA vendor selection meet-

- ings to consider the appointment of the provider of the EU Hub and National Blueprint Systems for the EMS authentication project
- » PGEU attended eHealth Stakeholder Group Meeting hosted by European Commission
- » PGEU attended the Personalised Medicines Manifesto launch at the European Parliament
- » PGEU attended the International Conference on Patient Safety in Primary Care organised by LINNEAUS-PC partnership under the FP7 framework in Frankfurt

- » PGEU addressed meeting on the coalition for Health Ethics and Society (CHES) on Promoting Health and Preventing Disease
- » PGEU attended the Joint Action on Health Workforce Planning
- » PGEU chaired a session of the 1st European Conference of Oncology Pharmacy, in Budapest

✦ October

- » Pharmacovigilance: the European Council approved amended legislation
- » Falsification: European Commission launched public consultation on a common logo for legally-operating online pharmacies/retailers
- » PGEU addressed the Centennial FIP Congress with presentations on the role of pharmacy technicians, non prescription medicines counselling, POM/NPM reclassification, pharmacy regulation and competition law, and the future of independent pharmacies
- » PGEU chaired FIP Stakeholder Roundtable on adherence in Amsterdam
- » PGEU attended the Project Steering Committee meeting of eHealth Governance Initiative hosted by the Austrian Ministry of Health
- » PGEU addressed Slovakian Pharmaceutical Congress

- » PGEU addressed Australian Pharmacy Congress in Melbourne
- » PGEU addressed GS1 Congress in Lisbon
- » PGEU attended the Project Group "Good governance for non-prescription drugs" meeting in London hosted by MHRA
- » PGEU attended the EU Health Policy Forum
- » PGEU addresses the European Pharmaceutical Students' Association (EPSA) Congress in Sofia

✦ November

- » Antimicrobial Resistance: European Parliament Public Health Committee adopts report
- » Pharmacovigilance: European Commission published consultation on phasing in new "black symbol" requirement
- » PGEU produced statement on Medicines Shortages
- » Water Framework Directive: MEPs voted on priority substance list



October
PIWG Meeting Group

- » Medicines' Shortages: EMA published reflection paper
- » PGEU produced joint statement with EAHP, the European Association of Hospital Pharmacists
- » PGEU published Charter of Collaboration with AESGP, the European Self Medication Association
- » PGEU elected Mr Maximin Liebl as PGEU President for 2013
- » The Pharmaceutical Society of the Federation of Bosnia Herzegovina joined PGEU
- » PGEU attended the meetings under the process of corporate responsibility of DG ENTR in Cyprus
- » PGEU attended the First Conference of Partners of the European Innovation Partnership on Active and Healthy Ageing
- » PGEU attended the 5th Pharmacovigilance Forum at EMA
- » PGEU addressed the Pharmaceutical Serialisation and Traceability Summit 2012 in Geneva

- » PGEU attended the EU Antibiotic Awareness Day 2012
- » PGEU attended the Patient Safety and Quality of Care Working Group of European Commission
- » PGEU addressed the Annual Conference of the Danish Pharmacies Association
- » PGEU attended the workshop for EFPIA's National Associations
- » PGEU attended eHealth Acceptance Conference organised by the project ICT for Health
- » PGEU addressed the Economist Global Healthcare Summit in London

December

- » Tobacco products: European Commission adopted proposal to revise the Tobacco Products Directive
- » Cross Border Directive: Commission published implementing directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State
- » Antimicrobial resistance: Parliament adopted resolution

- » PGEU launched European Community Pharmacy Blueprint for optimisation of health outcomes to individual patients and value for health systems across Europe (in English, French, Bulgarian, Estonian, Italian, Polish, Portuguese, Slovak and Spanish)
- » PGEU addressed the international conference 'Pharmacy News' in Lithuania



October
Slovakian
Pharmaceutical
Congress

December
*Launch of
Blueprint in
Cyprus*



In Challenging Times.... Advancing Community Pharmacy Practice

The ultimate goal of pharmacy practice as well as modern health care is to provide patients with the best and most cost-effective care possible. The fact that **community pharmacy is very often the first and last point of the patient's interaction with health system**, extending from general wellness advice to the dispensing of medication where appropriate or signposting to other sources of care, uniquely positions community pharmacy network in the health system.

Healthcare systems are currently undergoing significant changes. New technology, increased standardisation, new forms of organisation, a focus on outcomes, all characterise a new era in the approach to health care. Community pharmacies, as an essential part of health systems, are not exempt from this process.

The community pharmacy network continues to play a significant role in helping national health systems to meet today's and tomorrow's challenges: changing demographics of the European population (growing number of elderly); changing risk factors to health, such as increased prevalence of diabetes, obesity, COPD and other chronic diseases; shortages of health workers (in particular general practitioners and nurses); complex and ever fragmented healthcare pathway and increasing economic pressure.

It is widely recognised (including by governments) that community pharmacy practice and its contribution to European health systems can be further developed through the provision of a wider range of pharmacy based services and better use of pharmacist competencies, bringing further efficiency to patient care.

In 2012, PGEU developed the **European Pharmacy Blueprint**. The Blueprint was launched on the 3rd December, 2012 and presents the commitment of European community pharmacists to optimise health outcomes to individual patients and to add value to health systems across Europe. It is now available in multiple European languages at www.pgeu.eu.

Following the 4 principle clusters of daily activities of the community pharmacy, introduced in the Blueprint, we have divided PGEU Annual Report 2012 accordingly.

The main PGEU activities in 2012 are described under these clusters in detail.



“ The community pharmacy network continues to play a significant role in helping national health systems to meet today's and tomorrow's challenges ”



I. Enhancing Medicines Safety and Access to Medicines

▪ Falsified Medicines

The fight against counterfeit medicines continues to be a priority for the pharmacy profession and for PGEU.

Following the adoption of the Falsified Medicines Directive in 2011, the European Commission now has the task of putting in place the technical framework which will allow for the authentication of medicines in the supply chain.

Electronic authentication of medicines will ensure that counterfeit medicines do not reach the hands of patients. Pharmacists are committed to playing their part. **In March 2012, the PGEU General Assembly adopted an historic Memorandum of Understanding with our sister associations from the research based pharmaceutical industry (EFPIA), pharmaceutical full**

line wholesalers (GIRP) and parallel distributors (EAEPC). The document expresses the commitment of the four organisations to work together to develop a system which is flexible, efficient, cost effective and practical. It sets out certain key legal and technical principles which would underpin such a system, including the development of a European 'Hub' database to ensure interoperability of national authentication systems.

The Hub would be established and managed by a non-profit company owned by the key stakeholders in the sector. This European Stakeholder Models ('ESM') would allow stakeholder expertise to help ensure that the system is as user friendly as possible, while maximizing the impact on patient safety and keeping costs down.

The four organisations will continue to work through 2013 on detailed technical specifications for the system. It is hoped that other stakeholders will join the project in due course.

▪ Recognition of cross-border prescriptions

The Directive on the application of patients' rights in cross-border healthcare approved in 2011, required the European Commission to facilitate recognition of prescriptions within the EU. This included a minimum list of elements to be included in prescriptions used by patients crossing borders.

The European Commission developed a list of the elements to be included in cross border prescriptions at the end of 2012, including authentication

of the prescription, identification of the patient and prescriber, and identification of the product (name, pharmaceutical form, quantity, strength and dosage regimen). The law established that in order to identify the product, medicines must be prescribed using the INN (a

“Community pharmacy is very often the first and last point of the patient's interaction with the health system”



Dominique Maraninchi
Professor, Director General of French Medicines Agency (ANSM)

The way medicines are procured, stored and dispensed and the information given by the pharmacist dictates the quality of their use, thus leading to rational or irrational use of medication. Rational use of medicine, safety and access largely depends on the community pharmacy network and expertise of the pharmacists.

As regulators, we very much value expertise of community pharmacists and their real life experience acquired from their contact with patients, such as elderly or polymedicated who usually do not participate in clinical trials. This knowledge is crucial in ensuring quality, safety and effectiveness of medicines.

“ Time spent solving problems caused by shortages, is time that could be better spent advising and caring for patients ”

special name given to active ingredient of medicines) or by brand name in case of biological medicines or when the prescriber deems it medically necessary.

By October 2013 Member States will need to adopt these common elements. The elements described in the European legislation may not match the national prescription elements. Member States may consider that adapting their national prescription elements to the European legislation is the easiest way to comply with the new law, although they are not obliged to do this. **This is an interesting example of developments at European level influencing aspects of our health systems and ultimately pharmacy practice which are normally thought to be purely national matters.**

■ **Medicine Shortages**

Making sure that the right patient gets the right medicine, at the right time, followed by the appropriate advice is the cornerstone of pharmacy practice. **The growing problem of medicine shortages is of great concern to community pharmacists and in some countries already affects their daily practice.**

At the beginning of 2012, PGEU conducted a survey among its members, in order to better understand the extent of medicine shortages in the EU. According to the survey results, although some countries are more affected than others, medicine shortages were reported by all respondents to the survey and the problem is increasing. A broad range of medicines is affected, including even basic medication such as aspirin⁹. The survey suggests that the prevalence of medicine shortages has increased in the past year- just in the UK over 1 million branded medicine supply failures occur each year¹⁰.

Time spent solving problems caused by shortages is time that could be better spent advising and caring for patients. An additional source of frustration among community pharmacists is the lack of communication about the shortage, its severity, causes and how long will it take to be resolved. This information, if it is provided in a timely and efficient manner, would allow pharmacists to serve their patients better and plan their practice and stock accordingly.

⁹ <http://www.bloomberg.com/news/2012-01-10/greek-crisis-has-pharmacists-pleading-for-aspirin-as-drug-supply-dries-up.html>

¹⁰ <http://www.appg.org.uk/APPG%20Pharmacy%20-%20Report%20of%20Inquiry%20Into%20NHS%20Medicines%20Shortages.pdf>

PGEU published a **Statement on Medicine Shortages** on 15th November 2012, inviting medicines supply chain partners, governments and EU Institutions to work closely together to better plan the supply of medicines in Europe, and to inform each other about possible shortages well in advance. This should help to ensure that **European patients needs are met and patients can receive their medicines on time.**

■ GDP

A very wide range of medicines and medical devices, including those requiring special storage conditions, such as cold chain products, are traditionally distributed in the pharmacy. In order to ensure integrity and high quality of medicines, pharmacies comply with complex regulatory requirements. Environmental parameters suitable for the storage of medicines are ensured at all times.

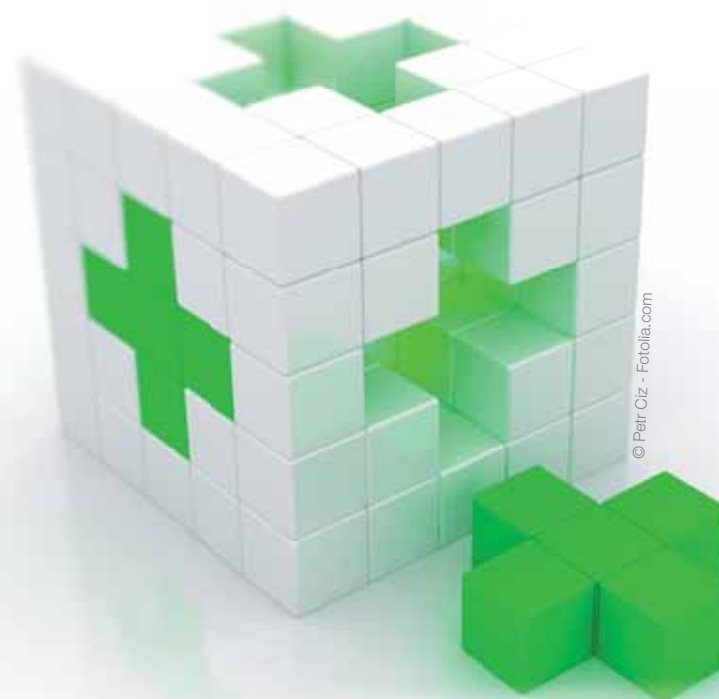
PGEU and its members supported the revision of the Guidelines on Good Distribution Practice in 2012. The current Guidelines, that date back to 1990's, needed to take into account changes and advances in practice in

connection with the appropriate storage and distribution of medicinal products.

Community pharmacy, as the last point of the supply chain before medicines reach the hands of patients, is the key factor in ensuring the quality and safety of medicines. Good Pharmacy Practice (GPP) guidelines complement Good Manufacturing Practice (GMP) guidelines and Good Distribution Practice (GDP) guidelines, and ensure the highest standards of medicines supply in Europe.

In the majority of EU member states, pharmacies receive multiple daily deliveries from wholesalers, and thus can effectively meet the needs of the population they serve without delays. Therefore it is essential that any changes to the Guidelines are proportionate, and do not place excessive burdens on the supply chain partners which may necessitate the lowering of current service standards in the pharmacies.

“ **Community pharmacy, as the last point of the supply chain before medicines reach the hands of patients, is the key factor in ensuring the quality and safety of medicines** ”



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II. Improving Treatment Outcomes of Individual Patients



Nicola Bedlington
Secretary General,
European Patients
Forum

The role of community pharmacists is critical – supporting patients, alongside other health professionals, to understand better their medication, and take it more effectively and safely. EPF values hugely the collaboration we enjoy with PGEU, getting this message across through joint policy and project initiatives such as ‘Chain of Trust’.

Chain of trust is a collaborative project on telehealth funded by the European Commission

■ Medication management

The management of medication by pharmacists maximises the benefits and minimises the risk inherent in the use of medicines by patients through better selection, optimisation and utilisation¹¹. Although pharmacists in different countries may provide medication management services in slightly different ways, **the goal of all pharmacists is to make sure that the medication is right for the patient and his or her health conditions and that the best possible outcomes from treatment are achieved.**

A good example of a successful medicines management programme is the pharmaceutical care project **Ad-hiérete** in Spain. The programme aims to improve adherence to treatment and is addressed to patients older than 65 years, chronically ill, polymedicated, and with a certain degree of dependency. It

builds on a successful pilot conducted in the village of Azuaga (Badajoz, Spain) in 2010 that showed an increase of adherence to treatment for this targeted population from 41.2% to 70.6% after a structured pharmacist intervention. **The programme is a commitment of the Council of Pharmacists of Spain and PGEU under the Active and Healthy Ageing Partnership Initiative presented to the European Commission in 2012.** The intention is to scale up the pilot, through involvement of a greater number of partners and making this service available to a wider population.

The core of this service is a pharmacist conducted patient assessment aimed at optimisation of therapeutic outcomes for individual patients. It is a pharmaceutical care service provided by a pharmacist during an individual appointment with the patient. The pharmacist performs a holistic patient assessment and identifies all medica-

“**The management of medication by pharmacists maximises the benefits and minimises the risk inherent in the use of medicines by patients through better selection, optimisation and utilisation**”

¹¹ Tuesca-Molina R, Guallar-Castillón P, Banegas-Banegas JR, Graciani-Perez Regadera A. Determinants of therapeutic compliance in elderly over 60 years old in Spain. *Gac Sanit* 2006;20(3):220-7.



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tions that the patient is taking. The pharmacist discusses how the medications are best taken and medication related problems, as well as detecting the risk of negative outcomes related to the medication. The initial assessment is followed up by a repeated pharmacist home visit or at the point of dispense. An individual patient care plan is proposed by a pharmacist in agreement with the patient and a treating doctor if necessary.

This programme aims to improve patient knowledge, adherence and use of medicines when establishing use and understanding, resolving ineffective medicine use, identifying side effects/medicine interactions; it also improves individual patient outcomes and cost effectiveness of the therapy, as well as reduces waste. Ultimately, the community pharmacist will report medication related and other problems identified to the physician, so that he/she may, in turn, adjust medication therapy at an early stage.

■ Integrated care

A major challenge for community pharmacists remains the delivery of effective, patient-centred and efficient services in collaboration with other healthcare professionals. **It is important to support professional interchange with all parties involved in the care of the patient in both secondary and primary care.**

To bridge this gap, a pharmaceutical record system (Dossier Pharmaceutique, abbreviated as DP) has been available in French hospital pharmacies since October 2012. The DP was set up by the French Chamber of Pharmacists in 2007 and now connects 97% of French community pharmacies. The DP was created on a voluntary basis with patient's consent and encompasses all medicines (POM and NPM) dispensed to the patient in the previous 4 months in any French community pharmacy. From now on hospital pharmacies will be connected to the system.

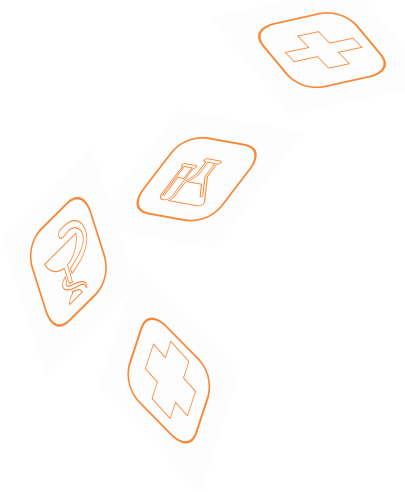
The aim of extending the DP to the hospital setting is to avoid medicines interactions and redundancies in treatment, while supporting coordination, quality and continuity of treatments as well as dispensation safety. During a pilot study undertaken in a hospital in Lunéville (NE France) 217 medication discrepancy cases were detected over 10 months. The shared DP would have allowed pharmacists to detect 78.3% of these medication discrepancies (63.1% treatments stopped unintentionally, 3.7% treatments added unintentionally, 11.5% dosage mistakes). In 4 months (since the implementation of the decree), 27% of French hospital pharmacies have applied to be connected to the DP system.

Following this best practice example, **the joint statement by PGEU and the European Association of Hospital Pharmacists (EAHP) was signed in November 2012. It highlights the need for multi-professional approaches to healthcare delivery in order to ensure integrated and seamless patient care.** It includes a call for improving systems of communication between health sectors when a patient transfers between hospital and community (and vice-versa), especially in relation to situations where changes are made to a patient's medication. PGEU and EAHP called for commitment from Governments to achieving multi-professional care, and for the integration of the multi-professional team concept within health professional education curricula.

“ A major challenge for community pharmacists remains the delivery of effective, patient-centred and efficient services in collaboration with other healthcare professionals ”



III. Improving Public Health



▪ Self-care

In 2012 PGEU undertook research in connection with pre- and post-qualification education and training of pharmacists in self-care by the European Commission Working Group on promoting good governance for non-prescription medicines. Research focused on education in non-prescription medicines, counselling and self-medication support. However it is important to note that self-care in the context of pharmacy practice is much broader and encompasses advice on:

- hygiene both general and personal,
 - nutrition which includes counselling on the type and quality of food eaten,
 - lifestyle including counselling on sporting activities, leisure, exercise etc.,
- as well as

- self-medication support, including a signposting (referral to other health professionals) role.

A brief questionnaire was designed to explore undergraduate pharmacy education in relation to self-care and self-medication. Questions were based on the findings and initial views found in the literature and identified by pharmacy practice experts. The questionnaire consisted of three main questions on subjects in pharmacy curriculum aiming to develop core competencies in clinical, responding to symptoms and communication aspects of the practice.

According to the survey results, subjects such as clinical pharmacy, internal medicine, therapeutics, and pharmaceutical care are part of the modern pharmacy curriculum. They prepare the pharmacy

workforce to respond effectively to patient's common ailments, symptoms and self-care needs, including in preventative therapy. This has the potential to substantially enhance the provision of appropriate medication, self-care advice and support in the pharmacy.

In conclusion, **pharmacists have unique insight into how people manage their medicines, especially those with chronic conditions, how they present to pharmacy, and what their needs are with respect to medicines.** The pharmacists' perspective is vital when creating self-care policies.

In 2012 PGEU and AESGP, the European organisation representing the self-medication industry, renewed their commitment to cooperate in their efforts to help ensure safe, effective and

innovative self-care. The Charter of Collaboration between the two organisations, which was first agreed in 1998, was adopted by the two associations in November 2012.

■ Pharmacovigilance: post-authorisation studies

Authorities rely on individual pharmacists to report any suspected side effects from medicines, a process known as pharmacovigilance. In the UK, the number of reports has increased by 122 % since 2011, following a new services introduced in pharmacies to help patients get used to taking a new medicines for the first time (the New Medicines Service). In 2012 UK pharmacists made 2,417 reports compared to 1,751 in 2011.

Nevertheless the pharmacists' role in pharmacovigilance goes beyond reporting of adverse drug reactions (ADRs) to the authorities. The unique position of community pharmacies, experts in medicines at the heart of communities, represents an exceptional research opportunity in the post-authorisation efficacy and safety of medicines. **Pharmacies can collect medicines' use as well as patient experience data, and assist National Authorities and manufacturers to help ensure systematic pharmacovigilance throughout the entire life cycle of the medicine.**

An example of this collaboration is the research study currently in place in Portugal to estimate adherence and persistence to oral bisphosphonates (OBP) in the Portuguese postmenopausal osteoporosis (PMO) population. Women over 50 years old that have initiated OBP in last 24 months were recruited through community pharmacies. Persistence data (e.g., refill dates and medication possession) are collected by an electronic capture system developed for electronic transfer of patients' sales data from pharmacies to the Center for Health Evaluation & Research (CEFAR), the research unit of the National Association of Pharmacies (ANF).

Community pharmacists are committed to assuming more responsibility in post-authorisation studies for pharmacovigilance, pharmacoecconomics and pharmacoepidemiological purposes.

■ Antibiotic Awareness

Numerous leftovers of or uncompleted antibiotic therapies are kept in the home medicine cabinets. This is a growing phenomenon since therapy duration in prescribing guidelines does not necessarily match the amount of tablets or other pharmaceutical form commercially available. **Antibiotic leftovers present a significant public health concern: not only do they encourage inappropriate self-medication, they often contain insufficient quantities for an effective**

“ **Pharmacists have unique insight into how people manage their medicines, especially those with chronic conditions, how they present to pharmacy, and what their needs are with respect to medicines** ”



Monika Kosinska
Secretary General,
European Public
Health Alliance

Community pharmacists are key frontline health staff, who are close to both the patient and their communities, making them a vital and often underutilised actor in public health. At a time when the optimal use of medicines and reducing costs of healthcare and increasing efficiency is at the forefront of policymakers priorities, the community pharmacist is essential to help achieve these goals.

In public health specifically, the central and primary role of the pharmacist needs to be better understood and exploited. Whether responding to public health crises, spreading public health messages, contributing to immunisation and vaccination strategies or offering public health services to the community, the contribution of the community pharmacist is an invaluable asset to achieving better health outcomes for all.



“Pharmacists play an important role in signposting patients, referring them to the doctor or other appropriate health service when medical examination or prescription treatment is considered necessary”

therapy and are useless for treatment of bacterial infections. This facilitates the emergence and spread of antimicrobial resistance. To address this growing problem, the Belgian Pharmacist Association (APB) in collaboration with the Belgian government has launched a public health campaign in Belgian community pharmacies.

In order to make pharmacists as well as the public aware of this problem, the Belgian government supplied all community pharmacies in Belgium with 20 stickers, stating that ‘antibiotics do not belong in a home medicine cabinet’. Pharmacists were asked to label all dispensed antibiotics with a sticker that urged the patient to return any antibiotic leftovers to the pharmacy. The dispensing software generated a pop-up message during every antibiotic dispensing act (software available in approx. 2600 Belgian pharmacies) to remind pharmacy staff about the initiative. It also monitored the impact of the project.

This initiative was well received by the pharmacists and has been effective. It addressed medicines supply and patient care, core aspects of pharmacy practice. Building on the success of the

programme, it will be repeated in 2013. With similar initiatives addressing antibiotic awareness **PGEU and its members actively contribute to the European Antibiotic Awareness Day. In 2012 PGEU joined ECDC’s Technical Advisory Committee of the European Antibiotic Awareness Day.**

▪ Screening programmes

During the launch of the European Cancer Week 2012 by European Partnership Action Against Cancer in Rome, Italy, Dr Racca, President of PGEU member Federfarma, presented results of a screening campaign organised by community pharmacies for the prevention of colorectal cancer. This campaign was targeted to people from 50 to 69 years old and took place in Italian community pharmacies. The main features of the campaign included:

- Initial specialised training provided by the Local Health Unit (LHU) to community pharmacists.
- Stocking a screening kit for the detection of fecal occult blood in every participating community pharmacy.

- In parallel, the LHU sent a letter to the targeted population inviting them to visit the closest pharmacy.
- Community pharmacists gave the kit to the patient after having recorded his/her consent and registering the patient's name and the screening kit barcode into the specific software provided by the LHU. This facilitated quick traceability of the process following direct contacts with a patient.
- Pharmacies collected the screening kits from patients and sent it via the logistical system of wholesalers to the LHU.

- Finally community pharmacies dispensed medicines prescribed by LHU's general practitioners with the objective of colon preparation. Community pharmacists recorded this dispensation and provided all the necessary pharmaceutical and health advice to patients.

The first results of the screening activity revealed that 40% of the target population (22,580 individuals) agreed to participate in the screening, leading to the identification of 3.3 % cases of patients affected by colon

rectal cancer and 7% of cases with a positive screening result requiring follow up care. Of these, 45% of the results detected intestinal polyps. The early identification of intestinal polyps represents a real added value of the screening activity, as the scheme managed to guarantee a hugely useful prevention of colon rectal cancer, given that 90 % of this cancer is caused by a degeneration of the intestinal polyps.

This is one of the examples of the many screening and health promotion campaigns that take place in com-

munity pharmacies across Europe. **Pharmacists play an important role in signposting patients, referring them to the doctor or other appropriate health service when medical examination or prescription treatment is considered necessary.**



“ PGEU and its members actively contribute to the European Antibiotic Awareness Day ”



COMMUNITY PHARMACY KEY FACTS & FIGURES



Community pharmacies are accessible to over 500 million EU citizens, 365 days a year, 24h a day



154,000
community pharmacies
in the EU

COMMUNITY PHARMACY KEY FACTS & FIGURES

Pharmacies are the most widely distributed healthcare facility in Europe.

COMMUNITY PHARMACIES



There are
154,000
community
pharmacies in the
EU¹. Pharmacies
are the most widely
distributed healthcare
facility in Europe.



Approximately **98%** of EU citizens can reach their nearest community pharmacy within **30 minutes**, while 58% of citizens indicate that their closest community pharmacy is within **5 minutes** reach from their work or home². Pharmacies in the majority of EU countries are required to ensure that premises have access for people with disabilities.

IN GENERAL PHARMACIES HAVE LONGER OPENING HOURS THAN OTHER HEALTH CARE SETTINGS AND THROUGH EXTENDED OPENING HOURS, ROTA AND NIGHT SERVICES ENSURE PATIENTS CAN ACCESS THEIR



SERVICES 24/7.



Community pharmacies are accessible to over **500 million EU citizens.** Among the 23 million people who visit a community pharmacy everyday are the most vulnerable and those with the least means.

¹ 154.000 is the number of community pharmacies in EU27 and candidate country Croatia. Source: PGEU database 2011.

² Survey of Chain of Trust Project, under EC Public Health Programme (Grant Agreement N° 2009 11 13).

COMMUNITY PHARMACISTS



Community pharmacies across EU employ **400,000 pharmacists**, as well as over **660,000** other pharmacy support staff and provide training sites for pharmacy students.

Computerisation of pharmacies is **99.99%**



Community pharmacists complete at least **5 years of university based education** (equivalent to a Master degree), including 6 months training in the pharmacy. In addition, community pharmacists acquire specific competencies and develop expert professional practice in the field of community pharmacy. They are required continuously to update their knowledge and skills to make sure they are 'fit for practice'. Continuing professional development or lifelong learning is a professional and ethical obligation of community pharmacists and is being reinforced in many EU countries.

Community pharmacists in the EU are **highly qualified healthcare professionals** with broader knowledge of medicines than any other healthcare professional.



For many years pharmacists have been in the **top 3** of the most trusted professions according to consumer surveys³.

³ PGEU Database 2011.

MEDICINES



According to the World Health Organization WHO, the cost of adverse drug reactions (ADRs), including hospitalisations, surgery and lost productivity, exceeds the cost of medicines in some countries⁷.


194,500 DEATHS A YEAR IN THE EU ARE DUE TO MISDOSE AND NON-ADHERENCE TO PRESCRIBED MEDICATION. NON-ADHERENCE IS ESTIMATED TO COST THE EUROPEAN UNION **€125BN ANNUALLY.**⁸

Over 9.5 billion prescription only medicine packs are dispensed in Europe annually⁵.




The great majority of medicines are prescribed in primary care setting and therefore dispensed in the community pharmacy.

The use of **multiple medications**, known as polypharmacy, is recognised as an increasingly serious problem in healthcare systems.



On average, the medicines budget is **17%** of the total health budgets.



More than **263,444**⁴ medicines are licensed in the EU.

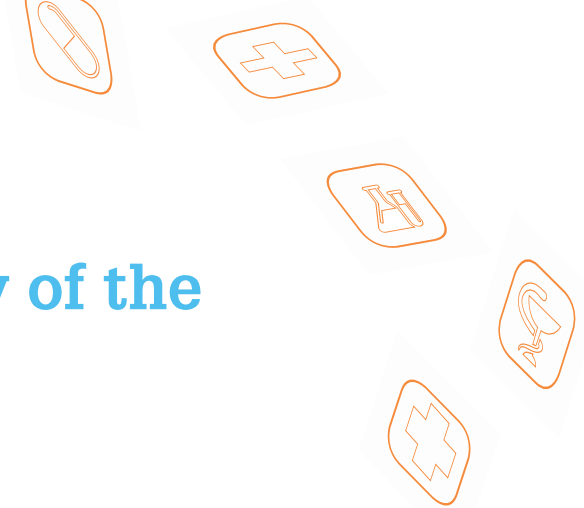
⁴ European Medicines Agency Data for 21 EU Member States, 2012.

⁵ IMS 2010 data.

⁶ OECD Health Data 2009.

⁷ World Health Organization (2008) Fact sheet No293. Medicines: Safety of medicines – adverse drug reactions. Geneva: World Health Organization.

⁸ Medi-Voice project http://cordis.europa.eu/fetch?CALLER=FP6_PROJ&ACTION=D&DOC=3019&CAT=PROJ&QUERY=1170700793308&RCN=75025.



IV. Contributing to the Efficiency and Quality of the Health Systems



Ab Klink, Professor in the Free University of Amsterdam, former Minister of Health, the Netherlands

Addressing medication related problems such as poor adherence and avoidable adverse reactions contributes to economic efficiency by helping to reduce absenteeism and increasing productivity and helps to reduce hospital referrals (and costs of health care itself). To realise these benefits however, the institutional framework of health systems and their reimbursement systems have to be seriously reframed. If we don't we run the risk that health care costs will grow as a result of the innovative initiatives.'

“ **Evidence shows that pharmacy interventions to improve the way patients take their medicines can make a real difference** ”

Pharmaceutical budgets are under unprecedented pressure in Europe. **Pharmacists in many countries are facing economic challenges, and in some cases these are severe.** However, perhaps too little attention is given to the capacity of pharmacists to contribute to economic efficiency. This was the theme of **the statement adopted by PGEU in March – “Sustainable European Community Pharmacies: Part of the Solution”**. Poor adherence to medicines and avoidable adverse drugs reactions present a significant cost for health systems. **Evidence shows that pharmacy interventions to improve the way patients take their medicines can make a real difference, by avoiding waste, improving the effect and impact of therapy, and avoiding more complex and expensive treatment in future.**

Equally, measures currently adopted by many European governments to

encourage the use of cheaper generic medicines through ‘generic substitution’ require the expertise of pharmacists to guide patients through the complex process of changing from one medicine to another or understanding what is the right medicine for them.

And of course in the network of pharmacies – the most widely distributed and accessible health infrastructure in Europe – governments and patients have an invaluable resource. Patients rely on the network not only for counselling on medicines, but also as a source of advice on a wide range of health related issues, the first step on the health service ladder. But in fact **there is vast potential to use pharmacists even more, through the provision of a wider range of pharmacy based services, including for example services aimed at detecting and better managing chronic disease.** This is a key



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consideration if health systems are to be sustainable in the coming years.

For these reasons, short term measures which undermine pharmacy viability risk contributing to a less cost effective health system in the future.

▪ **Directive on the Recognition of Professional Qualifications**

The Directive on the Recognition of Professional Qualification is the European law which allows professionals to move to work in other European countries on the basis of mutual recognition of qualifications. **Pharmacists enjoy a particular regime of ‘automatic’ recognition together with other 5 ‘sectoral professions’: doctors, midwives, nurses, vets, dentist and architects.** Other professions not subject to European harmonization need to follow a rather more complicated procedure

which compares elements of training in the two member states involved. ‘Automatic’ recognition requires a minimum harmonization of the training of the relevant professions.

During 2012 the three main EU law-making Institutions: Commission, European Parliament and Council, considered a proposal to modernise the Directive. The objective of the reform was to further facilitate the provision of services and simplify administrative procedures. New elements were proposed such as a European Professional Card, an alert mechanism for cases of misconduct, and new rules for the testing of languages.

PGEU saw the reform as the unique opportunity to bring up to date the chapter regulating the pharmacy profession. A survey was undertaken for this purpose among PGEU mem-

bers. The results showed that the list in the Directive describing the basic pharmacist activities dating from 1985 is out of date and does not reflect current pharmacy practice. Therefore pharmacists are currently calling for a reform of the list to properly reflect the scope of pharmacy practice in all EU Member States. **European Pharmacists would like to add the following activities:**

- Sourcing, dispensing of safe and secure medicinal products;
- Medicines management and provision of information on health related issues;
- Supporting individual patients on non-prescription medicines and self-care;
- Contributing to public health campaigns.

“ The use of cheaper generic medicines through ‘generic substitution’ requires the expertise of pharmacists to guide patients through the complex process of changing from one medicine to another or understanding what is the right medicine for them ”



Looking Forward

2013 will be a period of intense activity for PGEU in the legislative area. New proposals in relation to Data Protection and Medical Devices will be debated by the European institutions. The new Directive on the Recognition of Professional Qualifications is likely to be adopted. Preparation for the implementation of electronic authentication of medicines as part of the Falsified Medicines Directive will continue. PGEU will ensure that the voice of pharmacy is heard in all these debates.

Beyond the immediate concerns of the European legislative process, PGEU will continue the work, begun in 2012 with the adoption of the European Pharmacy Blueprint, of developing a vision for the future of pharmacy as an integral part of European health systems.

In a time of unprecedented challenges, community pharmacy continues to deliver a vital health service to millions of European citizens each day. In the cities, towns, villages, avenues, streets and squares of Europe, the community pharmacy symbols still shine brightly. But no profession can afford to stand still. The winds of technological and economic change are blowing across the continent.

As we have shown in our Annual Report, pharmacists are committed to developing their practice to meet the challenges of health systems on the 21st century. **Professional community pharmacy services have, we believe, never been more relevant, and never more needed: To improve health outcomes. To promote cost effectiveness in medicines use. To better manage the growing burden of chronic disease. To tackle the problems of an aging and increasingly medicated society.**

Paradoxically however, in some EU countries pharmacies are declining in numbers or facing the threat of closure. Our vision must be therefore not simply of a profession optimising its vital contribution to the health and well-being of our citizens, through for example developing a wider range of pharmacy based services, but also of a sustainable network and an economic climate which allows professionalism to flourish.

Pharmacists need to lead the way in showing how they can make health systems more effective. Policy makers need to reflect on how they might make better use of the asset they have in the pharmacy network, and how to ensure its sustainability. Let us not miss the huge opportunity that lies before us.



PGEU Governance 2012

PGEU BOARD

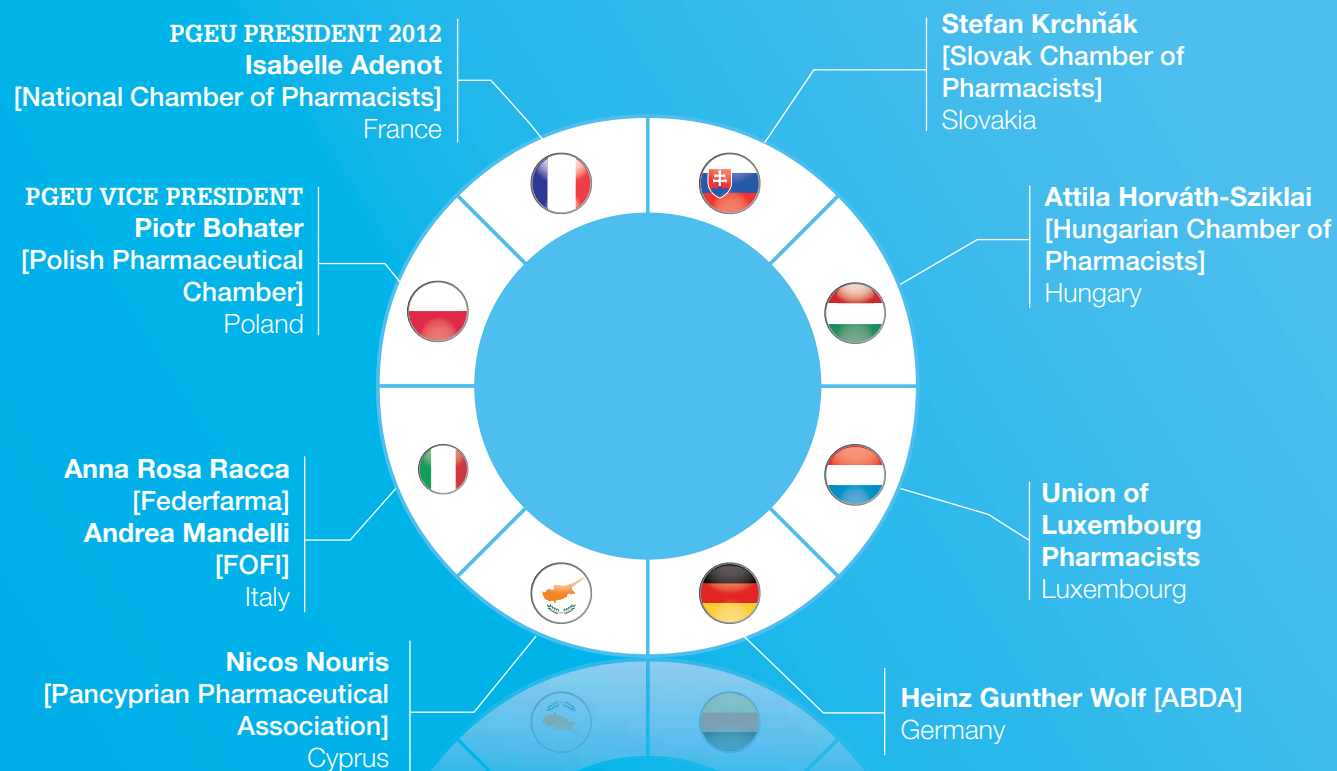


PGEU PRESIDENT 2012
Isabelle Adenot



PGEU VICE PRESIDENT
Piotr Bohater

PGEU EXECUTIVE COMMITTEE



PGEU Members 2012

1 | Austria

- ❖ Austrian Chamber of Pharmacists
- ❖ Austrian Pharmacy Owners Association

2 | Belgium

- ❖ Belgian Pharmaceutical Association (APB)
- ❖ Belgian Order of Pharmacists (ODF)

3 | Bosnia-Herzegovina

- ❖ Pharmaceutical Society of Federation of Bosnia and Herzegovina

4 | Bulgaria

- ❖ Bulgarian Pharmaceutical Union

5 | Croatia

- ❖ Croatian Chamber of Pharmacists
- ❖ Croatian Pharmaceutical Society

6 | Cyprus

- ❖ Pancyprrian Pharmaceutical Association

7 | Czech Republic

- ❖ Czech Chamber of Pharmacists

8 | Denmark

- ❖ Association of Danish Pharmacies

9 | Estonia

- ❖ Estonian Pharmacies Association

10 | Finland

- ❖ Association of Finnish Pharmacies

11 | France

- ❖ Conseil Central de l'Ordre Nationale des Pharmaciens
- ❖ Fédération des Syndicats Pharmaceutiques de France (FSPF)
- ❖ Union des Syndicats de Pharmaciens d'Officine (USPO)
- ❖ Union Nationale des Pharmaciens de France

12 | Germany

- ❖ Federal Union of German Pharmacists Associations (ABDA)

13 | Greece

- ❖ Panhellenic Pharmaceutical Association

14 | Hungary

- ❖ Hungarian Chamber of Pharmacists

15 | Ireland

- ❖ Irish Pharmacy Union

16 | Italy

- ❖ Federation of the Order of Italian Pharmacists (FOFI)
- ❖ Italian Pharmacy Owners Federation (Federfarma)

17 | Luxembourg

- ❖ Syndicat des Pharmaciens Luxembourgeois

18 | TFYR Macedonia

- ❖ Pharmaceutical Chamber of Macedonia

19 | Malta

- ❖ Malta Chamber of Pharmacists

20 | Netherlands

- ❖ Royal Dutch Pharmaceutical Association (KNMP)

21 | Norway

- ❖ Norwegian Pharmacy Association

22 | Poland

- ❖ Polish Pharmaceutical Chamber

23 | Portugal

- ❖ National Association of Pharmacies
- ❖ Pharmaceutical Society of Portugal

24 | Romania

- ❖ Romanian College of Pharmacists
- ❖ Romanian Pharmacy Owners Association

25 | Serbia

- ❖ Pharmaceutical Society of Serbia
- ❖ Association of Private Pharmacists of Serbia

26 | Slovakia

- ❖ Slovak Chamber of Pharmacists

27 | Slovenia

- ❖ Slovenian Chamber of Pharmacists

28 | Spain

- ❖ General Council of Spanish Pharmacists

29 | Sweden

- ❖ Swedish Pharmacy Association

30 | Switzerland

- ❖ Société Suisse des Pharmaciens

31 | Turkey

- ❖ Turkish Pharmacists Association

32 | United Kingdom

- ❖ National Pharmacy Association
- ❖ Pharmaceutical Society of Northern Ireland
- ❖ Royal Pharmaceutical Society of Great Britain



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